Steven A. Zalesin (Admitted *Pro Hac Vice*)
sazalesin@pbwt.com
Catherine A. Williams (Admitted *Pro Hac Vice*)
cawilliams@pbwt.com
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, New York 10036
Telephone (212) 336-2110
Facsimile (212) 336-2111

Tammy B. Webb (SBN 227593)
tbwebb@shb.com
SHOOK, HARDY & BACON LLP
One Montgomery St., Suite 2700
San Francisco, California 94104
Telephone (415) 544-1900
Facsimile (415) 391-0281

Attorneys for Defendant The Coca-Cola Company

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

SHANA BECERRA, individually and on behalf of a class of similarly situated persons,

Plaintiff,

v.

THE COCA-COLA COMPANY,

Defendant.

CASE NO. 17-cv-05916-WHA

DEFENDANT'S NOTICE OF MOTION AND MOTION TO DISMISS FIRST AMENDED COMPLAINT

SUPPORTING MEMORANDUM OF POINTS AND AUTHORITIES

Date: February 8, 2018
Time: 8 a.m.
Judge: Hon. William Haskell Alsup

NOTICE OF MOTION AND MOTION TO DISMISS

TO THE COURT AND ALL PARTIES AND COUNSEL:

PLEASE TAKE NOTICE that on February 8, 2018 at 8 a.m., or as soon thereafter as counsel may be heard, in the United States District Court, Northern District of California, San Francisco Division, located at 450 Golden Gate Avenue, Courtroom 12, San Francisco, CA 94102, before the Honorable William Haskell Alsup, Defendant The Coca-Cola Company will and hereby does move this Court for an order dismissing Plaintiff's First Amended Complaint ("FAC") in its entirety and with prejudice.

This motion is made pursuant to Federal Rules of Civil Procedure 12(b)(6), and is based on the following grounds: (1) Plaintiff's claims are expressly preempted by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*., because Plaintiff seeks to impose requirements for food labeling that are not identical to federal requirements; (2) Plaintiff's consumer protection claims are barred as a matter of law under California's safe harbor doctrine because federal and state law clearly permit the challenged conduct; and (3) Plaintiff has not stated a claim for breach of the implied warranty of merchantability.

The Motion is based on this Notice of Motion and Motion to Dismiss, the Memorandum of Points and Authorities and accompanying declarations, the FAC and all other pleadings on file in this matter, and upon such other written and oral argument as may be presented to the Court.

Dated: January 16, 2018

PATTERSON BELKNAP WEBB & TYLER LLP

SHOOK, HARDY & BACON LLP

By: /s/ Steven A. Zalesin
Steven A. Zalesin (*pro hac vice*)

Attorneys for The Coca-Cola Company

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Regulations

Rules

Other Authorities

MEMORANDUM OF POINTS AND AUTHORITIES

STATEMENT OF ISSUES TO BE DECIDED

1. Are Plaintiff's state-law claims, which seek to impose food labeling requirements that differ from those imposed by the Federal Food, Drug and Cosmetic Act, expressly preempted by that statute?

2. Does California's safe harbor doctrine bar Plaintiff's consumer protection challenge to food labeling practices that are clearly permitted by federal and state law?

3. Has Plaintiff plausibly alleged that Diet Coke is unfit for the ordinary purpose for which it is used?

PRELIMINARY STATEMENT

The Federal Food, Drug and Cosmetic Act ("FDCA") establishes uniform definitions for terms that commonly appear on food labels throughout the United States. One such term is "diet," which the statute and its implementing regulations define to mean "low calorie or reduced calorie." In addition to dictating this general definition, the FDCA contains a separate provision that explicitly permits use of the term "diet" in the brand name of a low calorie soft drink.

This straightforward definition of "diet" is consistent with longstanding industry usage and consumer understanding of that term. Diet Coke, the product at issue in this case, has been on the U.S. market for 35 years, during which time it has gained almost universal recognition among consumers as a low calorie alternative to Coca-Cola's traditional cola. The term "diet" also identifies numerous other low calorie soft drinks, in Coca-Cola's portfolio and throughout the beverage industry. Indeed, the ubiquity of "diet" soft drinks, and those products' familiarity to consumers, is a primary reason that Congress expressly authorized use of the term "diet" to identify this category of low calorie products.

Plaintiff Shana Becerra nevertheless seeks to impose a new definition of "diet," and to prevent Coca-Cola from calling its iconic product "Diet Coke." Plaintiff does not dispute that Diet Coke is a zero calorie beverage that satisfies the FDCA definition of a "diet" soft drink. Rather, she alleges that recent scientific studies cast doubt on the proposition that artificial sweeteners such as

the aspartame used in Diet Coke "contribute to healthy weight management." (FAC ¶ 48) Plaintiff thus alleges that Coca-Cola's use of the term "diet" violates the FDCA's broad prohibition on food label statements that are "false or misleading." And because it purportedly breaches this overarching FDCA duty, Plaintiff alleges, the name "Diet Coke" also violates California's consumer protection statutes and warranty laws. She seeks, on behalf of herself and other California purchasers, restitution and an injunction requiring Coca-Cola to abandon its decades-old brand name.

Plaintiff's outlandish request is expressly preempted by federal law. In enacting the Nutrition Labeling and Education Act of 1990 ("NLEA"), Congress determined that it was essential that food labels be uniform throughout the Nation, and that state and local authorities not impose labeling standards or definitions that differ from federal requirements. To that end, Congress empowered a single federal agency, the U.S. Food and Drug Administration ("FDA"), to adopt uniform definitions of common food labeling terms. And it expressly preempted individual states, including courts acting under color of state law, from imposing food-labeling requirements that are not *identical* to most federal requirements. Where, as here, the FDCA provides a uniform definition for a term such as "diet," a private litigant may not seek to utilize state law to redefine that term.

Nor can Plaintiff use the FDCA's prohibition of "false or misleading" label claims to evade preemption. This Court has previously rejected similar attempts to turn this general proscription into an end-run around the statute's preemptive effect. The result can be no different here. In addition to being expressly preempted, Plaintiff's claims run afoul of California's safe harbor doctrine, which bars consumer protection claims that challenge conduct explicitly authorized by statute or regulation. And her allegations fail as a matter of law to state a claim for breach of the implied warranty of merchantability. The FAC should be dismissed in its entirety.

BACKGROUND

A. The FDCA Preempts Most State Labeling Requirements That Are Not Identical To Federal Law

The NLEA amended the FDCA to "establish uniform food labeling requirements" throughout the United States. *Reid v. Johnson & Johnson*, 780 F.3d 952, 959 (9th Cir. 2015)

(internal quotation marks omitted). As a result of the NLEA's passage, the FDCA and its implementing regulations impose a comprehensive "scheme governing labels on food products," to the exclusion of non-identical state or local requirements. *Guttmann v. Nissin Foods (U.S.A.) Co.*, 2015 U.S. Dist. LEXIS 92756, at *5 (N.D. Cal. July 15, 2015) (Alsup, J.).

In enacting the NLEA, Congress sought to establish "consistent, enforceable rules pertaining to the claims that may be made with respect to the benefits of nutrients in foods." H.R. No. 101-538, at 7-8 (1990). Uniform nationwide rules, Congress determined, would help consumers "make sense of the confusing array of nutrition labels that confront [them] every time they enter the supermarket." 136 Cong. Rec. H5836-01 (July 30, 1990) (statement of Rep. Waxman).

In order to ensure the rules' uniformity, Congress deemed it necessary to "prevent state and local governments from adopting inconsistent requirements … with respect to the claims that may be made about nutrients in foods." H.R. No. 101-538, at 8. Congress did not act lightly in forcing states out of the business of food-label regulation. Rather, it authorized FDA to commission the U.S. Institute of Medicine to study the issue in depth and catalogue the various state laws that the FDCA would displace. *See* Institute of Medicine, *Food Labeling: Toward National Uniformity*, National Academy Press (Washington D.C. 1992). Ultimately, Congress concluded that preempting inconsistent state requirements would be "fair to both consumers and industry," because a uniform interstate scheme would require "disclosure of all valid and relevant information to the consumer, while providing the industry with uniformity of law … that will permit them to conduct their business of food distribution in an efficient and cost-effective manner." *See* 136 Cong. Rec. H5836-01 (July 30, 1990) (statement of Rep. Madigan); *see also* 136 Cong. Rec. S16607 (Oct. 24, 1990) ("It is wrong to permit each of the 50 States to require manufacturers … to display different health and diet information on identical products sold throughout this country.") (statement of Sen. Hatch).

In accordance with this goal, the FDCA provides that no state "may directly or indirectly establish … any requirement … that is ***not identical*** to the requirement[s]" of various food-labeling provisions of the statute. 21 U.S.C. § 343-1(a)(1)-(5) (emphasis added). A state requirement is

preempted if it "imposes obligations" that "[d]iffer from those ***specifically imposed*** by or contained in the applicable provision (including any implementing regulation)." 21 C.F.R. § 100.1(c)(4) (emphasis added). This federal preemption scheme reflects Congress's considered judgment that "the net benefits from national uniformity in these aspects of the food label outweigh the loss in consumer protection that may occur as a result." 58 Fed. Reg. 2462, 2462 (Jan. 6, 1993).

B. Federal Law Authorizes Use of the Word "Diet" on the Label of Diet Coke

Both the FDCA itself and its implementing regulations authorize use of the term "diet" on low calorie soft drinks such as Diet Coke. The statute provides that low calorie soft drinks marketed prior to 1989 (as was Diet Coke) may continue to use the term "diet" in their brand names, so long as they satisfied the FDA regulation applicable to "diet" claims in force at that time. Current FDA regulations, meanwhile, provide that a soft drink marketed after 1989 may be labeled as "diet" if it satisfies the present-day regulation governing use of that term. While there are some differences between the pre-1989 regulation and the current one, the definition of "diet" has not changed: FDA has consistently defined the term to refer to a food with low or reduced calorie content. Because it meets this simple standard, Diet Coke is properly labeled as "diet" under federal law.

1. Low Calorie Soft Drinks Marketed Prior to 1989

FDA first defined the term "diet" in 1978, more than a decade before the NLEA was enacted. It did so after finding that a "common standard" for such label designations could assist consumers in managing their dietary intake. *See* 43 Fed. Reg. 43248, 43257 (Sept. 22, 1978). To achieve this objective, FDA adopted a straightforward definition of "diet" as "suggesting usefulness as [a] low calorie or reduced calorie food[]," and imposed clear standards for the latter two terms. 21 C.F.R. § 105.66(c), (d), (e) (1978).[1] It then authorized use of the term "diet" on products that qualified as "low calorie" or "reduced calorie" and were labeled as such. *Id.* This regulation was in effect when, in 1982, Coca-Cola introduced Diet Coke, the low calorie analogue to its flagship cola product. (*See* FAC ¶¶ 1, 11) Other low calorie soft drinks branded as "diet" soon followed.

[1] At that time, FDA regulations permitted a food to be identified as "low calorie" if it contained fewer than 40 calories per serving and 0.4 calories per gram. *See* 21 C.F.R. § 105.66(c) (1978).

By the time the NLEA amendments were enacted in 1990, "diet" had become so ubiquitous on low calorie soft drinks that Congress gave manufacturers of those products explicit statutory license to continue to use that term. Section 343(r)(2)(D) of the FDCA provides that, subject to the general prohibition on false or misleading labeling, a "soft drink" may use the term "diet" if (1) the term is part of the product's brand name; (2) that brand name was in use prior to October 25, 1989; and (3) "the use of the term 'diet' ***was*** in conformity with section 105.66"—the regulation defining "diet"—at that time. 21 U.S.C. § 343(r)(2)(D) (emphasis added). Congress thus provided that, while FDA might change the definition of "diet" in the future, pre-1989 soft drinks whose labels complied with the 1989 definition were "grandfathered" and could continue to use the term. At the same time, Congress gave preemptive effect to Section 343(r), which encompasses the "grandfathering" provision and governs all "nutrient content" claims. 21 U.S.C. §§ 343(r); 343-1(a)(5).

The context of the "grandfathering" provision makes clear that it was specifically intended to codify FDA's original definition of "diet" for pre-1989 soft drinks. Section 343(r)(2)(D) immediately follows a parallel provision that—again subject to the general prohibition on false or misleading labeling—authorizes any claim relating to nutrient content that is part of a product's brand name where (1) the name was in use before October 25, 1989; and (2) it does not "use[] terms which are defined in the regulations of the [FDA]." 21 U.S.C. §§ 343(r)(2)(C), 343(r)(2)(A)(i). This provision did not cover Diet Coke because "diet" had already been defined by FDA regulation as "suggesting usefulness as [a] low calorie or reduced calorie food[]." 21 C.F.R. § 105.66(e) (1978). Congress's decision to adopt a separate "grandfathering" provision for diet soft drinks, and to reference FDA's then-current definition of "diet" in that provision, reflects its approval of that definition when used on soft drinks.

The reference in Section 343(r)(2)(D) to the FDCA's general prohibition on "false or misleading" labeling does not undermine or weaken that endorsement, but simply provides a safeguard against improper manipulation of the "grandfathering" scheme. *See* 21 U.S.C. § 343(r)(2)(D) (providing that "diet" claims on soft drinks are "subject to paragraph [343](a)"); §

343(a) (prohibiting food labels that are "false or misleading in any particular"). Section 343(r)(2)(D) permits use of the term "diet" on any soft drink whose label "was in conformity" with the FDA definition ***as of 1989***. The current FDA regulation implementing the provision confirms that "diet" is a permissible descriptor for a soft drink that used the term as part of its brand name before October 1989, and "whose use of that term was in compliance with § 105.66 . . . ***on that date***." 21 C.F.R. § 101.13(q)(2) (emphasis added). Accordingly, absent the general prohibition on "false or misleading" labeling, these provisions could be read to permit such a beverage to retain the "diet" name indefinitely, even if its calorie content increased and it ceased to qualify as a low or reduced calorie product. Section 343(r)(2)(D)'s incorporation of Section 343(a) prevents manufacturers from engaging in such manipulation.

2. Low Calorie Soft Drinks and Foods Marketed After 1989

Although Section 343(r)(2)(D) made FDA's original definition of "diet" permanently applicable to pre-1989 diet soft drinks irrespective of subsequent changes to the definition, no such changes have actually been adopted. After passage of the NLEA amendments, FDA issued numerous new regulations, including a revised version of Section 105.66—but left its longstanding definition of "diet" undisturbed. The amended Section 105.66, issued in 1993, continues to define "diet" as a term "suggesting usefulness as [a] low calorie or reduced calorie food[]." 21 C.F.R. § 105.66(e).[2] FDA's decision to re-affirm its definition of "diet" after passage of the NLEA was the result of careful consideration. The agency explained in a 1991 Notice of Proposed Rulemaking that its original definition "provide[d] for the term 'diet' for use when a food is represented as being ***useful in reducing caloric intake*** or maintaining body weight," and that the term "ha[d] often been used on foods that are virtually free of calories, such as specially formulated soft drinks." 56 Fed. Reg. 60421, 60438 (Nov. 27, 1991) (emphasis added). Aware of this widespread use, FDA opted for

[2] FDA did, however, make minor revisions to the underlying definitions of "low calorie" and "reduced calorie" in the 1993 amendments. Under current FDA regulations, a food qualifies as "low calorie" if it (1) has a "reference amount customarily consumed" of greater than 30 grams; and (2) it does not provide more than 40 calories per reference amount customarily consumed. *See* 21 C.F.R. §§ 105.66(c), 101.60(b)(2).

continuity with respect to the term. Responding to a request for guidance from the soft drink industry regarding post-NLEA standards, it explained that "the agency [was] continuing to define the term 'diet' in its regulation, specifically in § 105.66," and that soft drinks introduced after 1989 could use the term so long as they were "in conformity with" that definition. 58 Fed. Reg. 2302, 2313 (Jan. 6, 1993). FDA further noted that all diet soft drinks then on the market—of which Diet Coke was the most prominent example—met that standard. It expressly stated that it was unaware of "any instances whereby line extensions for 'diet' soft drinks would not be in conformity with § 105.66." *Id.*[3]

The updated version of Section 105.66 did reflect some revisions from the prior version, including a proviso that terms such as "diet" could not be used if they were false or misleading. 21 C.F.R. § 105.66(e). But once again, this proviso simply prohibits foods that do not satisfy the definition of "diet" from being labeled as though they do. FDA made that purpose clear when promulgating the regulation. Using formulated meal replacements (another product governed by Section 105.66) as an example, FDA explained that "***if a food that is not a formulated meal replacement purported on its label to be a formulated meal replacement*** … FDA would consider the food to be [improperly labeled]." It then clarified that the new proviso would permit FDA "to ***take action against any food that uses terms such as 'diet'*** … ***in this manner***." 58 Fed. Reg. 2427, 2428 (Jan 6. 1993) (emphases added). Accordingly, as in Section 343(r)(2)(D), the qualifier regarding "false or misleading" claims complements the definition of "diet" by limiting the term's use to products that actually satisfy the regulatory definition.

[3] FDA's continued endorsement of "diet" as communicating "low or reduced calorie" is also consistent with the lay understanding of that term. Many popular dictionaries define "diet," the adjective, as low in calories or sugar, and some specifically refer to its common use on soft drinks. *See, e.g., Diet, New Oxford American Dictionary* (3d ed.) ("[as modifier] (of food or drink) with reduced fat or sugar content: diet soft drinks"); *Diet* (adj.), *Merriam-Webster's Collegiate Dictionary* (11th ed.) ("1: reduced in or free from calories <a *diet* soft drink>"); *Diet* (adj), *The American Heritage Dictionary of the English Language* (5th ed.) ("2a. Having fewer calories. b. Sweetened with a non-caloric sugar substitute.").

3. Application to Diet Coke

Section 343(r)(2)(D) of the FDCA authorizes the term "diet" for pre-1989 low calorie soft drinks. At the same time, FDA regulations specify that (1) pre-1989 soft drinks may use the term if, on October 25, 1989, their labels complied with Section 105.66 "as that regulation appeared in the Code of Federal Regulations ***on that date***"; and (2) soft drinks "marketed after October 25, 1989 may use the term … provided they are in compliance with the ***current*** [Section] 105.66 of this chapter." 21 C.F.R. § 101.13(q)(2) (emphases added).

Each of these provisions constitutes a separate and independent authorization of Diet Coke's brand name. At the time Section 343(r)(2)(D) was enacted, Diet Coke had been on the market for seven years. Then, as now, Diet Coke contained zero calories per serving, and in accordance with the requirements of Section 105.66, was labeled as low calorie. *See* Declaration of Edward Ryan ("Ryan Decl.") Ex. A; *see also* 21 C.F.R. § 105.66(c), (e) (1978).[4] Diet Coke also complied with the separate regulatory requirement that all foods using the term "diet" include on their labels certain general nutritional information. *See* 21 C.F.R. § 105.66(a) (1978). Diet Coke's use of "diet" in its brand name is thus permitted under the "grandfathering" provision of Section 343(r)(2)(D) and its implementing regulation.

Diet Coke's brand name is also permitted by 21 C.F.R. § 101.13(q)(2), which provides for use of the term "diet" on post-1989 soft drinks that comply with the current requirements of Section 105.66. Those requirements are substantially the same as the ones that applied in 1989, and Diet Coke's current label complies with them. *See* Ryan Decl., Ex. B; *see also* 21 C.F.R. § 105.66(e).[5]

---

[4] Product labels that are referenced and relied upon in a complaint may properly be considered on a motion to dismiss. *See McKinniss v. Sunny Delight Beverages Co.*, 2007 U.S. Dist. LEXIS 96108, at *9-10 n.1 (C.D. Cal. Sept. 4, 2010); *Guttmann*, 2015 U.S. Dist. LEXIS 92756, at *5 n.1.

[5] Section 105.66(b), which imposes labeling requirements for food made with "nonnutritive ingredients," does not apply to Diet Coke because, among other reasons, aspartame is classified as a nutritive sweetener. *See* 46 Fed. Reg. 38285 (Jul. 24, 1981) (describing aspartame as a "nutritive sweetener"); *Additional Information about High-Intensity Sweeteners Permitted for use in Food in the United States*, WWW.FDA.GOV ("[A]spartame, the only approved nutritive high-intensity sweetener, contains more than two percent of the calories in an equivalent amount of sugar."). Nor does Section 105.66(d), which governs comparative "reduced calorie" claims, apply to Diet Coke,

C. Plaintiff's Allegations

Plaintiff does not allege that Diet Coke fails to satisfy FDA's definition of "diet" as "low calorie or reduced calorie." Rather, she contends that the FDCA's general prohibition on "false or misleading" label statements gives private litigants like her carte blanche to impose an entirely different definition of that term. She claims that Coca-Cola's use of the term "diet" suggests not only that Diet Coke is low in calories, but that it will, in some unspecified manner, "assist in weight loss . . . or healthy weight management." (FAC ¶ 15) She also claims that Coca-Cola "reinforces this message" through its advertisements— though the three advertising images she cites do not refer even obliquely to weight management, and she does not claim to have read or relied on them when purchasing Diet Coke. (FAC ¶ 16)

Plaintiff maintains that this implicit message regarding "weight management" is false because—according to her interpretation of the available scientific evidence—artificial sweeteners such as aspartame "interfere with the body's ability to properly metabolize calories" and may "lead[] to weight gain and increased risk of metabolic disease, diabetes, and cardiovascular disease." (FAC ¶ 2) She thus asks the Court to disregard the FDCA definition of "diet," and to find that the name Diet Coke is false or misleading because it does not live up to her understanding of what a "diet" beverage should be. On this basis, Plaintiff seeks damages and injunctive relief on behalf of herself and other California consumers under California's Unfair Competition Law ("UCL") (Cal. Bus. and Prof. Code §§ 17200 *et seq*.), False Advertising Law ("FAL") (Cal. Bus. and Prof. Code §§ 17500 *et seq*.), Consumer Legal Remedies Act (Cal. Civ. Code §§ 1750 *et seq*.) ("CLRA"), and its express warranty and implied warranty of merchantability laws (California Commercial Code §§ 2313(1); 2314(1)).[6]

---

since Diet Coke's label does not include a statement comparing its calorie content to that of any other product.

[6] The same day she filed this case, Plaintiff also filed complaints against Pepsico and Dr. Pepper Snapple Group, asserting substantially similar claims in connection with those companies' diet soft drinks. *See Becerra v. Pepsico, Inc.*, 17-cv-5918 (N.D. Cal.) (filed Oct. 16, 2017); *Becerra v. Dr. Pepper Snapple Group, Inc.*, 17-cv-5921 (N.D. Cal.) (filed Oct. 16, 2017).

As a factual matter, the scientific evidence on which Plaintiff relies is (charitably) equivocal. None of the studies cited in the FAC evaluates the effects of aspartame specifically, let alone of Diet Coke. Every one of the studies that observes some correlation between artificial sweetener consumption and weight gain cautions ***against*** an inference of causation, and a few express outright skepticism of any causal connection.[7] Perhaps for these reasons, Plaintiff's theory has not gained widespread acceptance among public health authorities: the U.S. Centers for Disease Control and Prevention ("CDC"), for example, recommends "diet[] or low-calorie beverages" as helpful for managing caloric intake and controlling weight.[8]

But the Court need not delve into the facts of this scientific "controversy" because Plaintiff's claims are, in any event, barred by law. Congress and FDA have defined "diet" in a manner that differs from Plaintiff's construction of that term. Diet Coke unquestionably satisfies the federally-prescribed meaning of "diet," and the FDCA expressly preempts any attempt to use state law to impose a different definition. California's safe harbor rule likewise bars Plaintiff's challenge to conduct that federal law explicitly permits. And her claim for breach of the implied warranty of

---

[7] *See, e.g.*, Sharon P. Fowler et al., "Fueling the Obesity Epidemic? Artificially Sweetened Beverage Use and Long-Term Weight Gain," Obesity, Vol. 16, No. 8, 1894-1900 (Aug. 2008) (noting that increased reliance on diet soft drinks by "individuals already on weight-gain trajectories" was "the most obvious possible explanation" for possible correlation between diet soft drink consumption and weight gain) (cited at FAC ¶ 25 and n.7); Rebecca J. Brown et al., "Artificial Sweeteners: A Systematic Review of Metabolic Effects in Youth," Int'l J. of Ped. Obesity, Vol. 5, No. 4, 305-12 (Aug. 2010) (noting that "the jury remains out regarding a possible role of increased artificial sweetener use" in the increased prevalence of obesity and diabetes) (cited at FAC ¶ 20 and n.2); *see also* Richard D. Mattes and Barry M. Popkin, "Nonnutritive Sweetener Consumption in Humans: Effects on Appetite and Food Intake and Their Putative Mechanisms," *Am. J. Clin. Nutr.*, Vol. 89, No. 1, 1-14 (Jan. 2009) (observing that "intervention trials consistently fail to document that [artificial sweeteners] promote weight gain, and observational studies provide only equivocal evidence that they might") (cited at FAC ¶ 19 and n.1); Meghan B. Azad et al., "Nonnutritive sweeteners and cardiometabolic health: a systematic review and meta-analysis of randomized controlled trials and prospective cohort studies," Can. Med. Ass'n J., Vol. 189, No. 28, 929-39 (July 2017) (noting "limited evidence for the effect of [artificial] sweeteners on BMI.") (cited at FAC ¶ 2 and n. 10). *See* Declaration of Jane Metcalf, Exs. A-D.

[8] *See* "Rethink Your Drink," Centers for Disease Control and Prevention, *available at* https://www.cdc.gov/healthyweight/healthy_eating/drinks.html (last visited January 16, 2018) (suggesting "water, diet, or low-calorie beverages instead of sugar-sweetened beverages").

merchantability is deficient as a matter of law. The FAC should thus be dismissed.

LEGAL STANDARD

To avoid dismissal under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation marks omitted). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice"; instead, the plaintiff must "plead[] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* Dismissal is warranted when the plaintiff fails to articulate a viable theory of recovery. *Lucia v. Wells Fargo Bank, N.A.*, 798 F. Supp. 2d 1059, 1072 n.4 (N.D. Cal. 2011).

ARGUMENT

I. ALL OF PLAINTIFF'S CLAIMS ARE EXPRESSLY PREEMPTED

A. Plaintiff's Claims Seek to Impose Requirements That Are Not Identical to Federal Law

Diet Coke's label is authorized by the FDCA and its implementing regulations because (1) the product satisfied the definition of "diet" in 1989 and (2) it satisfies that definition today. *See* 21 U.S.C. § 343(r)(2)(D); 21 C.F.R. §§ 101.13(q)(2), 105.66(e). Plaintiff, however, seeks to use California law to impose additional requirements for the use of the term. She maintains that Diet Coke may be labeled as "diet" only if she is satisfied that its consumption will contribute to "healthy weight management." (FAC ¶ 48)

Plaintiff's claims are expressly preempted. The FDCA squarely bars state or local food-labeling requirements that are "not identical" to most federal requirements. 21 U.S.C. § 343-1(a). The Ninth Circuit has thus held that a private plaintiff may not "seek[] to enjoin and declare unlawful the very statement that federal law permits and defines." *Carrea v. Dreyer's Grand Ice Cream, Inc.*, 475 Fed. App'x. 113, 115 (9th Cir. 2012). In *Carrea*, the plaintiff asserted that the claim "0g Trans Fat" was misleading when used on a product that, in fact, contained a small amount of trans fat. The court held that the "0g Trans Fat" claim was, like "diet," a "nutrient content claim"

governed by Section 343(r) and that, accordingly, the plaintiff could not use state law to "impose a burden … that is not identical to the requirements under Section 343(r)." *Id.* The court further concluded that the plaintiff's claim would impose such a burden, because FDA regulations expressly permit products containing less than 0.5 grams of trans fat per serving to express their trans-fat content as zero. *Id.* The claim was thus preempted. *Id.*; *see also Perez v. Nidek Co.*, 711 F.3d 1109, 1118-19 (9th Cir. 2013) (finding claim expressly preempted because the plaintiff "effectively [sought] to write in a new provision to the FDCA").

This Court has likewise dismissed consumer protection claims that seek to impose additional requirements for the use of terms defined by Section 343(r). In *Guttmann v. Nissin Foods Co.*, 2015 U.S. Dist. LEXIS 92756, at *6-9 (N.D. Cal. July 15, 2015) (Alsup, J.), the Court, citing *Carrea*, dismissed a claim alleging that the statement "0g Trans Fat" was false and misleading in light of the presence of a small amount of trans fat. The Court emphasized that the challenged statement was "governed by Section 343(r)" and accompanying "FDA … regulations," and that "[s]tates are expressly preempted from establishing requirements for food labeling that are inconsistent with those requirements"—such as, in that case, a requirement that trace amounts of trans fat be disclosed. *Id.* at *5-6. Similarly, in *Backus v. ConAgra Foods, Inc.*, 2016 U.S. Dist. LEXIS 92355 (N.D. Cal. July 15, 2016) (Alsup, J.), the plaintiff challenged the claim "70% Less Saturated Fat"—which was likewise permitted by 21 C.F.R. § 101.13, the FDA regulation implementing Section 343(r)—but which the plaintiff argued was misleading because the product contained large amounts of artificial trans fat. This Court found that the plaintiff's complaint sought to "impose an obligation not imposed by the applicable [FDCA] provision," and was therefore preempted. *Id.* at *12-13.

Numerous other courts in this District have reached the same result. *See, e.g., Bronson v. Johnson & Johnson, Inc.*, 2013 U.S. Dist. LEXIS 54029, at *13 (N.D. Cal. Apr. 16, 2013) (challenge to antioxidant label claims preempted where the "label at issue fulfills each of the labeling requirements for antioxidant claims" set out in regulations promulgated pursuant to Section 343(r)); *Gustavson v. Wrigley Sales Co.*, 961 F. Supp. 2d 1100, 1123 (N.D. Cal. 2013) ("Because [defendant's] calorie-related claims appear to comply with all applicable federal regulations, any

finding that these claims are unlawful and deceptive would impose requirements not identical to the FDA's regulations"); *Samet v. P&G*, 2013 U.S. Dist. LEXIS 86432, at *20 (N.D. Cal. June 18, 2013) ("Express preemption is especially appropriate where the practice identified by the plaintiff is explicitly governed by either the FDCA or its regulations, and the defendant is in compliance with those requirements.").[9]

This principle governs here. Diet Coke's brand name is explicitly authorized by both Section 343(r), the FDCA section governing "nutrient content" claims, and 21 C.F.R. § 101.13, which implements that section through regulation. 21 U.S.C. § 343(r)(2)(D); 21 C.F.R. § 101.13(q)(2). Both have preemptive effect. 21 U.S.C. § 343-1(a)(5). Plaintiff's attempt to use state law to "impose a burden … that is not identical to the[se] requirements" is preempted. *Carrea*, 475 Fed. App'x at 115.[10]

As this Court has held, the FDCA's preemption clause bars even challenges to claims that—

---

[9] *See also Lam v. Gen. Mills, Inc.*, 859 F. Supp. 2d 1097, 1103 (N.D. Cal. 2012) (holding that FDCA and FDA regulations expressly preempted plaintiff's claim challenging "fruit flavored" and "naturally flavored" statements because statements complied with regulations governing such claims); *Gitson v. Trader Joe's Co.*, 2014 U.S. Dist. LEXIS 33936, at *41 (N.D. Cal. Mar. 14, 2014) (collecting cases) ("Courts have routinely found express preemption in the food-misbranding context when a plaintiff has attempted to sue over conduct that does not violate the FDCA or its accompanying regulations."); *Chacanaca v. Quaker Oats Co.*, 752 F. Supp. 2d 1111, 1114 (N.D. Cal. 2010) (because "0 grams trans fat" constitutes a nutrient content claim, it is covered by Section 343(r), which implicates the FDCA's express preemption provision); *see also Peviani v. Hostess Brands, Inc.*, 750 F. Supp. 2d 1111, 1119-20 (C.D. Cal. 2010) (finding express preemption where plaintiff's state-law claims sought to impose an obligation for trans fat disclosure that was not required by federal law); *Red v. Kroger Co.*, 2010 U.S. Dist. LEXIS 115238, at *4-7 (C.D. Cal Sept. 2, 2010) (finding express preemption where defendant's products were compliant with FDCA regulations); *In re Quaker Oats Maple & Brown Sugar Instant Oatmeal Litig.*, 2017 U.S. Dist. LEXIS 174394, at *17 (C.D. Cal. Oct. 10, 2017) (same).

[10] Federal law preempts not only plaintiff's FAL, UCL, and CLRA claims, but her breach of express and implied warranty of merchantability claims as well. *See Guttmann v. Nissin Foods (U.S.A.) Co.*, 2015 U.S. Dist. LEXIS 92756, at *9 (N.D. Cal. July 15, 2015) (Alsup, J.) (dismissing breach of express warranty claim as expressly preempted by FDA regulations); *Pardini v. Unilever United States, Inc.*, 2014 U.S. Dist. LEXIS 7900, at *26 (N.D. Cal. Jan. 22, 2014) (finding warranty claims arising out of serving-size and nutrient claims to be preempted); *Chacanaca*, 752 F. Supp. 2d at 1118 ("The Supreme Court has clarified that, in the context of express preemption provisions, the term 'requirements' reaches beyond positive enactments like statutes and regulations, to embrace common-law duties and judge-made rules." (citing *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431, 443 (2005)).

like "0g Trans Fat" on a product that contains some trans fat—are arguably ***literally false***. *Guttmann*, 2015 U.S. Dist. LEXIS 92756, at *9. Here, Plaintiff's assertion that Diet Coke's label is "misleading" rests on her interpretation of tentative and contradictory scientific evidence: as noted in one of the studies she cites, "the jury remains out" on the question of a relationship between diet soft drink consumption and weight gain.[11] If private plaintiffs were permitted to use state law to rewrite food-labeling rules on the basis of such nascent scientific theories, those rules would be subject to constant change and confusing interstate variation, as differing courts arrived at differing interpretations of the science. This would sabotage Congress's overarching goal of "uniformity of law … [to] permit [manufacturers] to conduct their business of food distribution in an efficient and cost-effective manner." *See* 136 Cong. Rec. H5836-01 (July 30, 1990) (statement of Rep. Madigan).

Moreover, even if Plaintiff could demonstrate that her proposed conditions for "diet" soft drinks would be consistent with, or complement, federal standards, that would not enable her to circumvent the FDCA's preemptive force. "[C]onsistency is not the test; identity is." *Turek v. Gen. Mills, Inc.*, 662 F.3d 423, 427 (7th Cir. 2011); *see also Red v. Kroger Co.*, 2010 U.S. Dist. LEXIS 115238, at *19 (where "FDA regulations specifically define the phrases at issue," they "do[] not present a situation in which FDA regulations provide a 'floor' upon which states can build."). All that matters is that Plaintiff's proposed standards are different from the FDCA's. They are and, for that reason, they are barred.

B. The FDCA's General Prohibition Against False or Misleading Label Claims Cannot Trump Its Specific Authorization of the Statement at Issue

Plaintiff does not dispute that Diet Coke, which contains zero calories per serving, satisfies the FDCA's definition of a "diet" soft drink as a "low calorie or reduced calorie" food. She relies instead on the statute's general prohibition against "false or misleading" claims, which is incorporated or referenced by the provisions governing the term "diet" and which, she claims,

[11] Rebecca J. Brown et al., "Artificial Sweeteners: A Systematic Review of Metabolic Effects in Youth," Int'l J. of Ped. Obesity, Vol. 5, No. 4, 305-12 (Aug. 2010) (Metcalf Decl., Ex. B) (noting that "the jury remains out regarding a possible role of increased artificial sweetener use in the obesity and diabetes epidemics") (cited at FAC ¶ 20 n.2).

supersedes those provisions' authorization of the term's use on low calorie soft drinks. 21 U.S.C. §343(r)(2)(D); 21 C.F.R. § 101.13(q)(2); *see also* FAC ¶¶ 42-43. In other words, she maintains that this general prohibition renders the FDCA definition of "diet" vulnerable to displacement by any state-law plaintiff who formulates a theory that the definition is inadequate.

Plaintiff is wrong. Numerous courts, including this one, have held that "a statement cannot be 'false or misleading' under Section 343(a) where the challenged conduct is expressly … permitted by FDA regulations." *Coe v. Gen. Mills*, 2016 U.S. Dist. LEXIS 105769, at *11 (N.D. Cal. Aug. 10, 2016) (internal quotation marks and citation omitted). This is true even where, as here, the provision governing the statement incorporates or references the FDCA's broad bar of "false or misleading" claims. Thus, in *Guttmann*, 2015 U.S. Dist. LEXIS 92756, at *7-8—the case involving a "0g Trans Fat" claim on a product with a small amount of trans fat—this Court rejected a virtually identical argument based on the FDCA regulation governing "nutrient content" claims. *See id*. (citing § 101.13(i)(3)). The relevant regulation, like the provisions at issue here, set forth clear parameters for claims about the level of a nutrient in a product, then immediately followed those parameters with the proviso that such claims could not be "false or misleading in any respect." *See* 21 C.F.R. § 101.13(i)(3). The Court noted that the "0g trans fat" statement complied both with the parameters for "nutrient content" statements and with a separate provision clarifying that less than 0.5g of trans fat per serving must be "expressed as zero" on product nutrition labels. *Id.* at *6-7 (citing *Chacanaca*, 752 F. Supp. 2d at 1118). It therefore dismissed the plaintiff's claims, finding that even the express ban on "false or misleading" nutrient content claims could not be read to strip these more specific provisions of their preemptive force. *Id.* at *7-8.

Other courts have reached the same conclusion, emphasizing that it would "eviscerate the strict preemption requirements" of the FDCA if its proscription of "false or misleading" statements overrode its pronouncements on specific labeling terms. *Gorenstein v. Ocean Spray Cranberries, Inc.*, 2010 U.S. Dist. LEXIS 143801, at *1, 4 (C.D. Cal. Jan. 29, 2010) (challenge to juice label preempted where defendant's description of its juice "complie[d] with all requirements of federal law."). In *Red v. Kroger Co.*, 2010 U.S. Dist. LEXIS 115238, the court dismissed a challenge to a

"cholesterol free" statement; there, as in *Guttmann*, the plaintiff relied on the regulatory provision prohibiting "false or misleading" claims about nutrient content. *See id.* at *10-11 (citing 21 C.F.R. § 101.13(i)(3)). The court noted that the FDCA contained detailed requirements for use of the term "cholesterol free" and that the products' compliance with those requirements "directly undermine[d] Plaintiff's argument that Defendant's use of [the term] [wa]s 'false and misleading.'" *Id.* at *13. To hold otherwise, the court concluded, would effectively place the requirements governing the use of "cholesterol free" "beyond the [FDCA's] express pre-emption provision":

> Given that federal regulations specify when the term[] "cholesterol free" can be used, Defendant's compliance with those regulations cannot be deemed to be "false and misleading." … While both 21 U.S.C. § 343(a) and 21 C.F.R. § 101.13(i)(3) prohibit labels from being "false or misleading" or from characterizing nutrient levels in a "false or misleading" way, ***21 U.S.C. § 343(r) and accompanying regulations describe, in detail, nutrient content claims that are permitted under federal law and, therefore, by definition, are not considered "false or misleading" under federal law.***

Id. at *13-15 (emphasis added); *see also Red v. Kraft Foods, Inc.*, 2010 U.S. Dist. LEXIS 146647, at *7 (C.D. Cal. July 26, 2010) ("Plaintiffs cannot rely on the 'false and misleading provision' to avoid the fact that they are seeking to impose a different requirement than any that are set out in § 101.62(d).").

So too here, Section 343(r) and its accompanying regulations describe "in detail" when products may be represented as "diet" soft drinks, and define "diet" as synonymous with "low calorie or reduced calorie." *See* 21 U.S.C. § 343(r)(2)(D); 21 C.F.R. §§ 101.13(q)(2), 105.66(e). Product labels that comply with these provisions, as Diet Coke's label does, are "by definition" not false or misleading. *Red v. Kroger*, 2010 U.S. Dist. LEXIS 115238, at *15.

Plaintiff's contrary argument is especially implausible in view of the context of the "false or misleading" qualifier, which makes clear that its purpose was to prevent the use of "diet" claims on full calorie products. As set forth in Background Section B(1), *supra*, absent the proviso, the "grandfathering" provisions applicable to pre-1989 diet soft drinks would authorize all such products to be branded "diet" in perpetuity, as long as they had complied with the FDCA ***in 1989***. *See* 21 U.S.C. § 343(r)(2)(D); 21 C.F.R. § 101.13(q)(2). The sensible reading of the proviso in the

"grandfathering" provision is that it was meant to prevent that type of abuse—not, as Plaintiff urges, to strip the remainder of the provision of all effect.

Indeed, when FDA amended Section 105.66 in 1993 and added the "false or misleading" qualifier to that regulation, it confirmed that the qualifier's purpose was simply to prevent higher calorie products from purporting to be "diet" foods. As discussed above, FDA explained in comments to the regulation that the amendments would permit the agency to "take action against any food that use[d] terms such as 'diet'" yet was not what it "purported on its label" to be. 58 Fed. Reg. 2427, 2428 (Jan 6. 1993). But FDA also retained, after careful consideration, the definition of "diet" as "suggesting usefulness as [a] low calorie or reduced calorie [food]." 21 C.F.R. § 105.66(e). Plaintiff would have the Court interpret the "false or misleading" qualifier as a loophole that allows private litigants to use state law to displace this federally-prescribed definition of "diet." There is no basis in law or reason for that result. Plaintiff cannot use the FDCA prohibition on "false or misleading" claims to sidestep preemption.

C. Plaintiff May Not Use 21 C.F.R. § 1.21(a), Another General Provision, to Evade FDCA Preemption

Plaintiff's alternative suggestion that Diet Coke's label violates 21 C.F.R. § 1.21(a), a separate FDA regulation, because it does not disclose that "the aspartame in Diet Coke can lead to weight gain" is unavailing for similar reasons. (FAC ¶ 45) Section 1.21(a), like 21 U.S.C. § 343(a), is a catch-all provision against misleading labels, and provides that a food label may be unlawful "if it fails to reveal facts that are … [m]aterial in light of other representations" on the label, or otherwise "[m]aterial with respect to consequences which may result from use." But both Section 343(r)(2)(D) and Section 105.66 enumerate what "material" facts must be disclosed alongside a "diet" claim: a soft drink bearing such a claim must contain a "low calorie" or "reduced calorie" disclosure. *See* 21 U.S.C. § 343(r)(2)(D); 21 C.F.R. § 105.66(e). Because the FDCA and its implementing regulations permit the term "diet" and specify the disclosures that must accompany it, the general language of Section 1.21(a) cannot be used to impose ***additional*** disclosure requirements. *See Gustavson v. Wrigley Sales Co.*, 2014 U.S. Dist. LEXIS 1693, at *30 (N.D. Cal.

Jan. 7, 2014) (holding that the absence of a disclosure alongside a claim that the FDCA "expressly allow[s]" cannot "possibly be an actionable omission under Section 1.21"). Plaintiff's attempt to impose such a requirement is therefore preempted.[12]

D. The Diet Coke Advertisements Referenced in the FAC Have No Bearing on the Preemption Analysis and Are Not Independently Actionable

Plaintiff's throwaway reference in the FAC to three Diet Coke print advertisements of unknown provenance does nothing to alter the conclusion that all of her claims are preempted. (FAC ¶ 16) As set forth above, the FDCA expressly preempts challenges to Coca-Cola's use of the word "diet" in the brand name for Diet Coke. Plaintiff's unremarkable observation that the brand name also appears in advertisements has no bearing on that fact.

To the extent that Plaintiff contends that the advertisements independently convey misleading messages regarding weight loss, and seeks to premise her consumer protection claims on those messages, her allegations are plainly insufficient. Though she describes the ads as "emphasiz[ing] [Diet Coke's] beneficial effects on body weight and composition," ***all*** of the descriptive text in the cited ads pertains solely to the undisputed fact that Diet Coke is free of sugar and calories. (FAC ¶ 16) (describing product variously as "no calories", "0% Calories", and "no sugar, no calories").[13] Accordingly, Plaintiff's allegations do not support her conclusory statement that the ads emphasize "body weight and composition."

Moreover, even if the ads did convey misleading messages, Plaintiff could not assert

[12] In any event, Congress has specified what disclosures are necessary regarding health risks in connection with nutrient content claims, and has exempted pre-1989 soft drinks from those requirements. *See* 21 U.S.C. § 343(r)(2)(B) (specifying disclosures that are required when a food contains a nutrient at a level that increases health risks); § 343(r)(2)(D) (providing that those disclosure requirements "do[] not apply" to diet soft drinks). By seeking a disclosure that Diet Coke "leads to weight gain," Plaintiff is attempting to impose just such a requirement.

[13] The remaining phrases and slogans—"all curves," "100% Love," and "Regret Nothing"—are not susceptible of being proven true or false, and are therefore not actionable. "The Ninth Circuit has held that 'generalized, vague and unspecific assertions constitut[e] mere 'puffery' upon which a reasonable consumer [cannot] rely.'" *Viggiano v. Hansen Natural Corp.*, 944 F. Supp. 2d 877, 894 (C.D. Cal. 2013) (quoting *Glen Holly Entm't, Inc. v. Tektronix, Inc.*, 343 F.3d 1000, 1015 (9th Cir. 2003)).

consumer protection claims arising from them, because she ***does not allege that she ever saw these ads***—let alone that she relied on them when deciding to purchase Diet Coke. Indeed, the FAC contains no allegations regarding when or where the ads appeared, so it is not even clear that they ran in the United States or within the statute-of-limitations period.

These omissions preclude Plaintiff from asserting consumer protection claims arising from the ads. It is well settled that a "party does not have standing to challenge statements or advertisements that she never saw." *Ham v. Hain Celestial Grp., Inc.*, 70 F. Supp. 3d 1188, 1197 (N.D. Cal. 2014); *see also Bruton v. Gerber Prods. Co.*, 961 F. Supp. 2d 1062, 1091 (N.D. Cal. 2013), *rev'd in part on other grounds*, 2017 U.S. App. LEXIS 6756 (9th Cir, Apr. 19, 2017) (holding that plaintiff "does not have standing to assert claims based on advertisements … she did not view personally"). This Court has accordingly dismissed consumer protection and breach of warranty claims arising from supposedly misleading marketing materials that the plaintiff did not claim to have seen. *See Gutierrez v. Wells Fargo & Co.*, 2009 U.S. Dist. LEXIS 38113, at *15 (N.D. Cal. May 5, 2009) (Alsup, J.) (dismissing CLRA claim where plaintiff "did not read or rely on any advertising or marketing material" and thus "has not established reliance or causation regarding any challenged [] advertising and marketing materials."); *see also Friedman v. Mercedes Benz USA LLC*, 2013 U.S. Dist. LEXIS 191915, at *12 (C.D. Cal. Apr. 9, 2013) (there can be no "actual reliance" if "the purchaser ***never saw*** the advertisement"); *Moncada v. Allstate Ins. Co.*, 471 F. Supp. 2d 987, 997 (N.D. Cal. Dec. 20, 2006) (dismissing breach of warranty claim for lack of reliance where there is "no evidence that [plaintiffs] actually read or relied upon the representations on the [web]site"). The result can be no different here. Plaintiff's desultory reference to three Diet Coke ads, which do not refer to weight loss and which she does not claim to have seen prior to her purchases, cannot salvage her consumer protection or breach of warranty claims.

II. THE SAFE HARBOR DOCTRINE BARS PLAINTIFF'S CONSUMER PROTECTION CLAIMS

Plaintiff's UCL, FAL and CLRA claims are also barred by California's safe harbor doctrine, which precludes application of these consumer protection statutes to conduct that a statute or

regulation "clearly permit[s]." *Cel-Tech Commc'ns, Inc. v. L.A. Cellular Tel. Co.*, 973 P.2d 527, 541 (Cal. 1999). Both state and federal laws, including federal regulations, can create safe harbors. *See Martin v. Medtronic, Inc.*, 2017 U.S. Dist. LEXIS 26350, at *48 (E.D. Cal. Feb. 24, 2017) (noting that the safe harbor rule "applies both to actions by the California legislature and actions by the U.S. Congress"); *Davis v. HSBC Bank Nevada, N.A.*, 691 F.3d 1152, 1166 n.3 (9th Cir. 2012) ("California intermediate courts agree with our conclusion that [federal] regulations can create safe harbors.").

Where Congress or a federal agency "has permitted certain conduct or considered a situation and concluded no action should lie, courts may not override that determination" through application of California's consumer protection laws. *Cel-Tech*, 973 P.2d at 541. The safe harbor doctrine has been held to bar consumer protection claims that, like Plaintiff's, arise from conduct authorized by FDA pursuant to its statutory authority under the FDCA. *See, e.g., Martin*, 2017 U.S. Dist. LEXIS 26350, at *49 ("To the extent that plaintiff's UCL claim challenges conduct previously authorized by the FDA during the [pre-market approval] process, FDA approval of [defendant's] labeling brings plaintiff's claims within the California safe harbor provision.").

Here, the conduct of which Plaintiff complains is expressly permitted by several statutes and regulations. First, Section 343(r)(2)(D) of the FDCA provides that a low calorie soft drink such as Diet Coke, whose brand name included the word "diet" prior to October 25, 1989, may continue to be labeled as such so long "the use of the term 'diet' was in conformity with section 105.66" at that time. 21 U.S.C. § 343(r)(2)(D). No clearer statutory "permission" is possible.

Second, FDA regulations implementing Section 343(r) provide for the same "grandfathering" for pre-1989 soft drinks, and further provide that post-1989 low calorie soft drinks may use the term "diet." *See* 21 C.F.R. §§ 101.13(q)(2), 105.66(e). Diet Coke falls within both of these regulatory authorizations. Third, the conduct is permitted by California's Sherman Food, Drug and Cosmetic Law, which adopts the provisions of the FDCA and its implementing regulations, including those cited above, as the law of the state. *See* Cal. Health & Safety Code §§ 109875 *et seq*.

Thus Congress, FDA, and the California legislature have each "considered [the] situation"

cited in Plaintiff's FAC, "permitted [the] conduct" in question, and "concluded no action should lie." *Cel-Tech*, 973 P.2d at 541. The California safe harbor doctrine therefore bars Plaintiff's consumer protection claims.[14]

III. PLAINTIFF'S BREACH OF IMPLIED WARRANTY CLAIM FAILS AS A MATTER OF LAW

Not only are all of Plaintiff's claims expressly preempted, her claim for breach of the implied warranty of merchantability fails for an additional reason: she has not plausibly alleged that Diet Coke is not "fit for the ordinary purposes for which such goods are used," as the statute requires. Cal. Com. Code § 2314(2)(c). To establish this element of an implied-warranty claim, a plaintiff must plead that the product "lack[ed] 'even the most basic degree of fitness for ordinary use.'" *Guttmann*, 2015 U.S. Dist. LEXIS 108217, at *6 (Alsup, J.) (quoting *Mocek v. Alfa Leisure, Inc.*, 114 Cal. App. 4th 402, 406 (Cal. Ct. App. 2003)). An allegation that the goods failed to "precisely fulfill the expectations of the buyer" is insufficient; instead, the plaintiff must plausibly allege that the product failed to achieve "a minimum level of quality." *Marcus v. Apple, Inc.*, 2015 U.S. Dist. LEXIS 2140, at *24 (N.D. Cal. Jan. 8, 2015) (Alsup, J.) (internal quotation marks and citation omitted).

In cases involving food products, this Court has interpreted this standard to require an allegation that the product was not "fit for human consumption." *Guttmann*, 2015 U.S. Dist. LEXIS 92756, at *12; *see also Bohac v. Gen. Mills, Inc.*, 2014 U.S. Dist. LEXIS 41454, at *32 (N.D. Cal. Mar. 26, 2014) (dismissing breach of implied warranty claim where plaintiff "has not, for example, alleged that the products were not edible or contaminated.").[15] Here, Plaintiff has alleged only that

---

[14] At least one court has extended the California safe harbor doctrine to breach of warranty claims arising out of the same conduct as consumer protection claims. *See Cruz v. Anheuser-Busch, LLC*, 2015 U.S. Dist. LEXIS 76027, at *19 (C.D. Cal. June 3, 2015) (where challenged label was approved by Alcohol and Tobacco Tax and Trade Bureau, plaintiff's claims—including claim for breach of express warranty—fell within safe harbor and failed "on this basis alone"). While this result makes perfect sense, this Court need not reach the issue here because Plaintiff's warranty claims are expressly preempted and suffer from other deficiencies.

[15] In *Guttmann*, this Court initially allowed the implied warranty claim to proceed because FDA had concluded that "no form of partially-hydrogenated oil," the ingredient at issue in that case, "was

Diet Coke may "lead[] to weight gain"—a charge could be made of most food products sold in the United States. (FAC ¶ 2) And her allegation that she would consider purchasing Diet Coke in the future "as a treat" belies any suggestion that it is unfit for human consumption. (FAC ¶ 56)

Even if Plaintiff had alleged that aspartame was unfit for human consumption, such an allegation would lack plausibility in light of FDA regulations endorsing aspartame's safety. *See* 21 C.F.R. § 172.804 ("[A]spartame may be safely used in food in accordance with good manufacturing practice as a sweetening agent and a flavor enhancer[.]"); *Additional Information about High-Intensity Sweeteners Permitted for use in Food in the United States*, WWW.FDA.GOV ("Aspartame is one of the most exhaustively studied substances in the human food supply, with more than 100 studies supporting its safety.").[16] Thus, even assuming that Diet Coke failed to satisfy Plaintiff's expectations, she has not alleged and cannot allege that Coca-Cola breached the implied warranty of merchantability. Her implied warranty claim must be dismissed for this reason as well.

CONCLUSION

Plaintiff seeks to impose requirements for the labeling of "diet" soft drinks that differ from those imposed by federal law, displacing the standards that have governed Diet Coke and countless other low calorie soft drinks for decades. Her claims are therefore preempted. In addition, her consumer protection claims are barred by California's safe harbor doctrine, and she cannot state a claim for breach of the implied warranty of merchantability. The FAC should be dismissed in its entirety. Because the deficiencies are not curable, the dismissal should be with prejudice and without leave to amend.

'generally recognized as safe.'" 2015 U.S. Dist. LEXIS 92756, at *11 (quoting 80 Fed. Reg. 34650 (June 17, 2015)). Here, by contrast, FDA has taken the exact opposite position with respect to both diet soft drinks and aspartame, the sweetening ingredient in Diet Coke.

[16] *Available at* https://www.fda.gov/food/ingredientspackaginglabeling/foodadditivesingredients/ucm397725.htm

Dated: January 16, 2018

Respectfully submitted,

PATTERSON BELKNAP WEBB & TYLER LLP
Steven A. Zalesin (Admitted *Pro Hac Vice*)
sazalesin@pbwt.com
Catherine A. Williams (Admitted *Pro Hac Vice*)
cawilliams@pbwt.com
1133 Avenue of the Americas
New York, New York 10036
Telephone (212) 336-2110
Facsimile (212) 336-2111

SHOOK, HARDY & BACON LLP
Tammy B. Webb (SBN 227593)
tbwebb@shb.com
One Montgomery St., Suite 2700
San Francisco, California 94104
Telephone (415) 544-1900
Facsimile (415) 391-0281

By: /s/ Steven A. Zalesin
Steven A. Zalesin

Attorneys for The Coca-Cola Company